Section 5 510(k) Summary

JUL 2 5 2013

510(k) Owner:	Arthrosurface, Inc. 28 Forge Parkway Franklin, MA 02038 Tel: 508.520.3003 Fax: 508.528.4604
Contact:	Dawn Wilson VP, Quality & Regulatory
Date of Preparation:	March 26, 2013
Trade Name:	Hammertoe Correction System
Common Name:	Intramedullary Bone Screw
Device:	Screw, Fixation, Bone
Regulation Description:	Smooth or threaded metallic bone fixation fastener
Regulation Number:	888.3040
Device Class:	Class II
Review Panel:	Orthopedic
Product Code:	HWC

Intended Use

Indicated for small bone fusion, fractures and inter-digital fusion of the fingers, toes and small bones.

Device Description

The Arthrosurface Inc's Hammertoe Correction System consists of two intramedullary bone screws, a taper lock pin and a set of instruments used for implant site preparation and delivery. The taper lock pin provides a press fit connection between the two screws with light contact pressure. The implant components are manufactured using implant grade titanium alloy and cobalt-chrome alloy.

Substantial Equivalency

The intended use, materials, design features and application of the Proposed Device are substantially equivalent to the following previously cleared and commercially marketed devices:

- Nextremity Solutions, LLC — K110445
  FlexFusion™ Fixation Implant
- Wright Medical Technology, Inc. — K101165
  PRO-TOE™ VO Hammertoe Implant System
- Tornier, Inc. — K990804
  StayFuse

Comparative Mechanical Testing was performed per relevant recognized standards. Results from static and dynamic cantilever bending, torque to failure, pull-out force, insertion-removal torque and axial disassembly force tests along with comparative dimensional analyses were used to support equivalence to predicate devices. Data from cadaveric testing were also reported.

The fundamental scientific technology of the proposed device has not changed relative to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 25, 2013

Arthrosurface, Incorporated
% Ms. Dawn Wilson
Vice President, Quality & Regulatory
28 Forge Parkway
Franklin, Massachusetts 02038

Re: K130859
Trade/Device Name: Hammertoe Correction System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: June 6, 2013
Received: June 11, 2013

Dear Ms. Wilson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith

For

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 Indications for Use Statement

510(k) Number (if known): K130859

Device Name: Hammertoe Correction System

Indications for Use:

Indicated for small bone fusion, fractures and inter-digital fusion of the fingers, toes and small bones.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Lori A. Wiggins

Division of Orthopedic Devices